

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO.,)
)
)
Plaintiff,)
vs.) Civil Action No.: 07-CIV-7343 (HB)
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)
SANOFI-AVENTIS, SANOFI-AVENTIS)
U.S. LLC and AVENTIS)
PHARMACEUTICALS, INC.)
Defendants.)
)
)
)

**DECLARATION OF EDWARD M. REISNER, ESQ. IN SUPPORT OF
SANDOZ INC.'S MOTION TO QUASH SUBPOENA**

EDWARD M. REISNER, ESQ., hereby declares under penalties of perjury:

1. I am senior counsel at Cohen, Pontani, Lieberman & Pavane LLP, counsel to Sandoz in this matter.
2. On or about August 17, 2007, Louisiana Wholesale filed a class action complaint in this Court seeking treble damages from defendants (collectively "Aventis") for violating the antitrust laws by filing a baseless Citizen Petition with the FDA for the purpose of delaying the FDA's approval of generic versions of the drug leflunomide marketed by Aventis under the trade name "Arava." A true and correct copy of the complaint is attached hereto as Exhibit A.
3. According to the complaint, once the FDA receives a Citizen Petition relating to a pending Abbreviated New Drug Application ("ANDA"), it will withhold approval of the ANDA until it has resolved the issues raised in the Citizen Petition. Complaint ¶6.
4. Plaintiff alleges that the result of Aventis' filing its meritless Citizen Petition (in March, 2005) was to delay for five months approval of ANDA's to market generic versions of Arava that had been filed by a number of drug companies including, Kali Laboratories, Barr Laboratories, TEVA Pharmaceuticals, Apotex

Corp. and Sandoz, which enabled Aventis to continue selling Arava at the elevated prices its market exclusivity permitted. *See* Complaint ¶¶7, 51.

5. The complaint alleges that, once the FDA denied Aventis's Citizen Petition on September 13, 2005, generic versions of leflunomide immediately entered the market and Aventis lost 80% of its market share within three months. *See* Complaint ¶¶8, 62.
6. On or about October 17, 2007, defendants filed a motion to dismiss the complaint, which has not yet been ruled on.
7. On or about October 22, 2007, Louisiana Wholesale served Sandoz with a subpoena which, in essence, required Sandoz to produce and permit inspection of virtually every single document in its custody or control referring or relating to the development of its generic version of Arava and its dealings with the FDA including, *inter alia*, all documents referring or relating to: Arava; "any Citizen Petition filed regarding leflunomide;" "plans for launching leflunomide...including launch updates, timelines, schedules, asset allocation analysis, sales forecasts...and commercial production;" Sandoz's ANDA and all correspondence with the FDA; development of Sandoz's formulation of leflunomide including "agendas and minutes of meetings" relating to that broad topic; all sales data (in units and dollars per package and dollars per unit) relating to leflunomide products identifying the customers, numbers of packages sold, returned, etc., price and unit adjustments; all IMS data (or other third-party generated marketing information) relating to leflunomide; all marketing forecasts; organization charts and telephone directories for the entire company and for each division or affiliate that had or has any involvement in the research, development, regulatory approval, manufacture, sale or marketing of any leflunomide product, etc. A true and correct copy of the subpoena is attached hereto as Exhibit B.
8. The subpoena also required Sandoz to appear for a deposition on December 17, 2007 at the offices of Garwin, Gerstein & Fisher LLP, 1501 Broadway, Suite 1416, New York, N.Y.
9. On or about November 6, 2007, I contacted Anne Fornecker, Esq. at Garwin, Gerstein (who had signed the subpoena), and requested that plaintiffs withdraw

the subpoena, which was clearly overly broad considering the issues in the litigation.

10. Ms Fornecker conceded that the subpoena was overly broad and said that plaintiffs' counsel (there are at least seven different firms representing various plaintiffs' groups) would be having a discussion concerning "what they really needed" and would get back to me after that meeting was held.
11. On or about November 9, 2007, I participated in a conference call with a number of plaintiffs' lawyers, who provided their reasons for the breadth of their subpoena.. While agreeing that the main issue was whether Sandoz would have been ready, willing and able to launch its generic leflunomide in April, 2005, but for the filing of the Citizen Petition, they conceded that they were asking for more documents and information than needed to make their case. They justified that overbreadth because; (a) they did not know what level of proof the judge would subject them to; and (b) they did not know what defenses Aventis would raise.
12. On or about November 14, 2007, Sandoz's counsel advised plaintiffs' counsel that Sandoz had still been negotiating with the FDA regarding technical issues relating to its ANDA which were not resolved until September 12, 2005. Thus, it is clear that the Citizen Petition only delayed approval of Sandoz's ANDA, at most, by one day and that Sandoz's "delay" would be irrelevant to any damages that the plaintiffs would be awarded if they prevailed in their suit.
13. Given that fact, the pendency of the motion to dismiss and the fact that a scheduling order had not even been entered yet in the case, I again requested that plaintiffs withdraw their overly broad subpoena. I also pointed out that, even though plaintiffs had expressed a willingness to somewhat narrow the scope of the subpoena (inadequately in Sandoz's view), as long as the subpoena was the operative document, no side-deal cut with plaintiffs would shield Sandoz from possible sanctions for noncompliance with its terms if Aventis objected, which was likely given that Sandoz's information would be helpful primarily to them. Although plaintiffs' counsel said that they would consider Sandoz's request and provide a response, to date none has been received.

14. Meanwhile, I have been informed that the principle witness who would be designated by Sandoz to testify in response to the subpoena is Beth Brannan, Sandoz Director of Regulatory Affairs. Ms. Brannan resides and works in Broomfield, Colorado, which also is where many of the documents sought by the subpoena are located.

November 26, 2007


Edward M. Reisner